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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,391	12/22/2003	Timothy Raymond Hirst	00833-P0043A	7178

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EXAMINER	
MONTANARI, DAVID A	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
05/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,391	HIRST, TIMOTHY RAYMOND	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,10-12,17,18,21,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 10-12,17, 18, 21, 26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/22/2007 has been entered.

2. Claims 1, 2, 10-12, 17, 21 and 26 are amended.

3. Claim 27 is newly added.

4. Claims 4-9, 13-16, 19, 20 and 22-25 are cancelled.

5. The art rejections of record, 102(b) and 103(a), have been withdrawn.

6. Claims 1-3, 10-12, 17-18, 21 and 26-27 are examined in the instant application.

Please note that the Examiner of record has changed. The Examiner of record now is David A. Montanari.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in The United Kingdom on 6/22/2001. It is noted, however, that applicant has not filed a certified copy of the 01153823.4 application as required by 35 U.S.C. 119(b).

Applicants indicate that an additional priority filing is not required for a PCT application, citing MPEP 201.11(a). See page 6 of Applicants' amendment.

Applicants' comments are noted, however appear to be in part incorrect. Examiner would agree that filing under 371 provides benefit to the PCT application, however this does not provide sufficient support for the claim to a foreign priority document. Specifically, 35 USC 365 provides the requirements for claim of a foreign priority document, referencing 35 USC 119(a). In this case, a certified copy of the foreign application is required to establish the claim for priority for the claimed invention.

Response to Arguments

Applicants contend they will submit in due course when an allowance is pending. However, this statement does not overcome the requirements of a completely submitted application for the necessity of claiming foreign priority. It is suggested that the priority documents be submitted in the next response by Applicant.

Specification/Drawings

The specification is objected to because page 46, Table I lists peptides longer than 10 amino acids that are not properly identified by a SEQ ID NO.

It is noted that Applicants have not responded to this objection in their remarks or by amendment to the specification.

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

In addition to table I on page 46, it is noted that the figure legends and figures comprise reference to protein and nucleic acid sequences.

Appropriate correction is required throughout the disclosure.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Response to Arguments

Applicants contend they will submit in due course when an allowance is pending. However, this statement does not overcome the requirements of a completely submitted application for the necessity of sequence compliance. It is suggested that the sequence CRF be submitted in the next response by Applicant.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 10-12, 17-18, 21 and 26-27 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an *in vitro* method of delivering a peptide to a cell expressing GM-1 ganglioside receptors on the surface of said cell comprising contacting said cell with a mutant B-subunit of *E. coli* heat labile enterotoxin (EtxB) or a mutant B-subunit of *Vibrio cholerae* cholera toxin (CtxB) covalently linked to said peptide, said mutant EtxB or mutant CtxB comprising one of the following point mutations within the region

spanning amino acid residues E51 to I58 of the β 4-α2 loop of EtxB or CtxB: CtxB(E51A), CtxB(Q56A), CtxB(H57A) and EtxB(H57S), thereby delivering said peptide into said cell; and a kit comprising said mutant EtxB or mutant CtxB covalently linked to said peptide; does not reasonably provide enablement for a method of delivering any agent to any target cell comprising contacting said cell with any mutant EtxB or any mutant CtxB, thereby delivering said agent to said cell resulting in treatment of the breadth of disorders and diseases encompassed by the claims for reasons of record in the office action mailed 9/22/2006.

Response to Arguments

Applicants argue in amendment filed 2/22/2007 that all claims have been amended to recite the particular mutants identified in the specification with the Examiner indicated in the previous Final Office Action to be enabled by the instant specification. Further Applicants argue that the Examiner has not explicitly entered a rejection of the claims on the grounds of enablement to assert that the claims are limited to an in vitro method and kit. However Applicants state that on pgs. 45-56 of the specification the particular mutants claimed are demonstrated to be active in cell lines and would be expected to be active in vivo. These arguments are not persuasive. The currently amended claims have overcome the enablement rejection in part, however the scope to in vitro is proper and maintained. The Non-Final Office Action mailed on 4/11/2006 addressed these concerns, especially to the broad spectrum of diseases that could be treated with the claimed method. The claimed method reads upon both in vitro and in vivo uses. Regarding the in vivo application of the claimed method the instant

specification as well as the pending claims are silent about specific factors and conditions that would enable an in vivo use. These include route of administration, dosage, vehicle, and expected efficacy. The skilled artisan at a minimum would require these basic requirements to be met to practice the claimed method in an in vivo setting. The previous Non-Final and Final Office Actions made clear that in vitro was a claim limitation that is required for enablement of the pending claims. Applicants have not provided any evidence or arguments that the claimed method would treat any disease or even a specific disease. The claimed method is drawn to delivering a peptide into the MHC class I antigen processing pathway of an antigen presenting cell to elicit a cytotoxic CTL response. However there is no teaching of what the claimed method would treat when used in vivo, thus leading the skilled artisan to practice the claimed method without a predictable degree of sucess. Thus for reasons of record and above the rejection is maintained.

Conclusions

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER